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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

7590 12/29/2004

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/752,899

**Applicant(s)**

BUNICK ET AL.

**Examiner**

Lakshmi S Channavajjala

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8-9-04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1-22-04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1615

### DETAILED ACTION

Upon reconsideration, the finality of the rejection of the last Office action is withdrawn and a new rejection has been issued.

Claims 1-13 are pending.

#### *Claim Rejections - 35 USC § 103*

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,495,177 to de Vries et al ('177) in view of US 5,380,541 to Beyts et al ('541).

'177 teaches orally dissolvable chewable tablet that is palatable and also dissolves rapidly in the mouth. The tablet of '177 includes active agents in the form of vitamin supplements such as folic acid, beta carotene, vitamin B12 etc, an effective amount alkyl polysiloxane to improve the texture of the supplement and a chewable base comprising a material selected from the group consisting of mannitol, sucrose, sorbitol, dextrose, cellulose derivatives etc (lines bridging col. 4-5). In particular, '177 teach an agglomerate base that comprises 90-99% by weight of carbohydrate-based material selected from dextrose, fructose, sucrose, dextrose monohydrate and maltodextrin or combinations thereof, which meets the limitation of claim 5; and a binder in an amount of 1-10% by weight of the composition (col. 10, lines 50-65). Instant specification does not define the term "substantially free". Further, the specification also states that the binders such as microcrystalline cellulose are less than 20% or even less than 10%. Thus, the amount of binder (1-10% by weight) taught by '177 is within the claimed range. '177 further teaches preparing carbohydrate agglomerate that has a particle size of 20 microns to 100 microns, the upper limit of which overlaps the claimed particle size (100 to 250 microns). For active agent, 177 teaches vitamins, minerals, nutrients and insoluble metal carbonates, oxides etc (col. 10,

Art Unit: 1615

lines 43-49) and teaches preparing the tablets by granulation (col. 11, lines 12-37). '177 teaches that chewable tablets are usually associated with disagreeable or bad taste and a bad mouth feel that is due to the chewy, gritty, oily, creamy or sticky consistency of the tablet and suggests addition of sweeteners such as saccharin, dextrose, sucrose, aspartame, fructose oligosaccharide etc (col. 1 and col. 8, lines 7-15) and states that the carbohydrate material in the agglomerate itself can be a sweetening agent in the composition. However, '177 fail to teach sucralose of instant claims.

'541 teach sucralose containing ingestible compositions such as medicaments, beverages, etc. '541 teaches that a synergy in obtaining sweetness is observed with sucralose and other saccharides such as glucose, fructose, mannitol, sorbitol, or fructose mixed with glucose. Example 1 of '541 shows the synergy of sucralose with various sweeteners such as fructose etc., and the list of sweetener blends with sucralose in col. 5, specifically mentions a combination of dextrose monohydrate and sucralose that reads on the instant claimed components. Further example 9 is directed to a peppermint tablet, which meets the description of a chewable tablet. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add a synergistic combination of sucralose with other sweeteners such as fructose, dextrose monohydrate, sucrose, glucose etc., of '177 or '541 because '177 desires the presence of a sweetener in the chewable tablet composition to avoid the unpleasant taste and '541 suggests that sucralose is effective in reducing the calorie level in the final preparation, and is much sweeter than the sucrose or other sweeteners. Accordingly, one of an ordinary skill in the art would have expected to sweeten the bad tasting or unpleasant tasting chewable tablet

Art Unit: 1615

composition of '177 by adding sucralose together with other sweeteners such that the sweetness intensity of the composition is increased due to the presence of sucralose.


***Response to Arguments***

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
December 22, 2004

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNICAL STAFF T600  
